510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number: k041871

B. Purpose for Submission: Notification of intent to manufacture and market the device: InterLab Microcal Control Serum for Protein Electrophoresis

C. Analyte: Quality control material (high and low) for the electrophoretic separation of proteins (Albumin, Alpha 1, Alpha 2, Beta, Gamma)

D. Type of Test: N/A

E. Applicant: InterLab Scientific Instruments srl

F. Proprietary and Established Names: Proprietary – InterLab Microcal Serum Controls Established – Quality Control Material (Assayed and Unassayed)

G. Regulatory Information:

1. Regulation section: 21 CFR 862.1660
2. Classification: Class I
3. Product Code: JJX
4. Panel: 75

H. Intended Use:

1. Intended use(s):
   The Microcal Normal and Abnormal Controls are lyophilized human sera intended for use as assayed quality control sera to monitor the precision of cellulose acetate based protein electrophoresis testing methods.
2. Indication(s) for use: See intended use above.
3. Special condition for use statement(s): For prescription use only
4. Special instrument requirements: Microtech System

I. Device Description: The device consists of lyophilized vials of human sera at a normal and abnormal level. Each vial requires reconstitution with 0.5 mL of

distilled water. Mean values and ranges for the Microtech System are provided in the labeling.

J. Substantial Equivalence Information:

1. Predicate device name(s): Kemtol Serum Controls Normal (k920927) and Abnormal (k920926) of Helena Laboratories

2. Predicate K number(s): Kemtol Serum Controls Normal (k920927) and Abnormal (k920926) of Helena Laboratories

3. Comparison with predicate:

InterLab Microcal Serum Normal and Abnormal Controls		
Item	**Device**	**Predicate**
Intended Use	InterLab Microcal Normal and Abnormal Controls are lyophilized human sera intended for use as assayed quality control sera to monitor the precision of cellulose acetate based protein electrophoresis testing methods.	Kemtrol Serum Control is to be used as a quantitative control for serum protein electrophoresis on cellulose acetate and agarose. It can also be used as a control for hemoglobin binding capacity of serum haptoglobin.
Form	Lyophilized	Lypholized
Matrix	Human Serum	Human Serum
Storage	2^{o} – 8^{o}C	2^{o} – 8^{o}C
Reconstituted Stability	12 days @ 2^{o} – 8^{o}C	5 days @ 2^{o} – 8^{o}C
Analytes	Albumin Alpha 1 Alpha 2 Beta Gamma	Albumin Alpha 1 Alpha 2 Beta Gamma
Levels	Normal & Abnormal	Normal & Abnormal
Electrophoresis Support Media	Cellulose Acetate	Cellulose Acetate Agarose

K. Standard/Guidance Document Referenced (if applicable): None referenced

L. Test Principle: N/A

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility: N/A

   b. Linearity/assay reportable range: N/A

   c. Traceability (controls, calibrators, or method): Lyophilized normal and abnormal control sera were reconstituted according to instructions reported in the insert sheet. Control serum samples were tested by electrophoresis on cellulose acetate supported on Mylar on a Microtech 648 instrument, manufactured by InterLab S. r. l. Electrophoretic tests were assayed using reagents and materials following the test procedure. Precision was calculated for intra-run and inter-run tests.

   Lyophilized normal and abnormal control sera was reconstituted after prolonged storage of about 3 years at 2^{o} – 8^{o}C. Preparation of control serum was performed according to the instructions reported in the insert sheet. Control serum samples were tested by electrophoresis on cellulose acetate supported on Mylar on a Microtech 648 instrument manufactured by InterLab S. r. l. The instrument provides densitometric percentages of each band versus the total content on each lane. The reconstituted serum was considered to be stable if mean values of each fraction fall within stated (assigned) ranges. Results demonstrate that the same batch of control serum assayed over multiple lots of strips yielded mean values that were within the stated range percentages over a period of three years.

   d. Detection limit: N/A

   e. Analytical specificity: N/A

   f. Assay cut-off: N/A

2. Comparison studies:

   a. Method comparison with predicate device: N/A

   b. Matrix comparison: N/A

3. Clinical studies:

a. *Clinical sensitivity:* N/A

b. *Clinical specificity:* N/A

c. *Other clinical supportive data (when a and b are not applicable):* N/A

4. Clinical cut-off: N/A

5. Expected values/Reference range: See the package insert for the assigned values and ranges.

N. Conclusion: The submitted information in this premarket notification is complete and supports a substantial equivalence decision.